UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/807,506	02/27/1997	VICTOR SMIT	236841/BO410	5096

22242 7590 07/02/2002

FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
BUDENS, ROBERT D	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/02/2002 29

Please find below and/or attached an Office communication concerning this application or proceeding.

08/807,506

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	29

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/2/02

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 94-132 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 94-132 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☒ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's request for a Continuing Prosecution Application is acknowledged. Applicant should note, however, as set forth in the Petition Decision, Paper No. 28, Applicant's Request should technically be a Request for Continued Examination (RCE), not a Continuing Prosecution Application (CPA). Accordingly, Applicant's Request has been treated as a Request for Continued Examination and **FINALITY** of the last Office Action is withdrawn.

The Examiner acknowledges Applicant's Preliminary Amendment, Paper No. 26, filed April 2, 2002. In view of Applicant's Preliminary Amendment, the status of the claims is as follows: Claims 1-93 have been canceled; Claims 94-132 are currently pending before the Examiner.

The objection to claims 126 and 128-129 under 37 C.F.R. 1.75(c) as being in improper form because a multiple dependent claim should only refer to other claims in the alternative and cannot depend from other multiple dependent claims is withdrawn in view of Applicant's Preliminary Amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 94-132 are rejected under 35 U.S.C. § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 94 and 122 are vague and indefinite in the recitation "is introduced" since it is entirely unclear what "is introduced" into said proteins. Amendment of claims 94 and 122 to more clearly define the invention would obviate this rejection. Claim 100 is vague and indefinite in the recitation "LDMS" since the abbreviation is not disclosed in the claims. Amendment of claim 100 to recite the full description of "LDMS" would obviate this rejection. Claims 104, 109, 111, 113, 115, 125 and 127 are vague and indefinite in the recitation "and/or" since it is entirely unclear what is encompassed by the claimed invention. Amendment of the claims to recite "and" or "or" would obviate this rejection. Claims 104, 108, 109, 121 and 130 are vague and indefinite in the recitation "e.g.," or "for example," or "for instance," or such similar language since it is unclear whether the limitations following the phrase are part of the claimed invention. Amendment of the claims to delete "e.g.," or similar language would obviate this rejection. Claim 104 is vague and indefinite in the recitation "gradually varying conditions" since it is entirely unclear to what extent and at what rate conditions are varied. Amendment of claim 104 to more clearly define the invention would obviate this rejection. Claims 107 and 112-114 are vague and indefinite in the recitation "close proximity" since it is unclear what distance would be encompassed by "close proximity." Amendment of the claims to more clearly define the invention would obviate this rejection. Claim 112 is vague and indefinite in the recitation "and a colony stimulating factor" since claim 112 is an improper Markush grouping. Amendment of claim 112 to correctly set forth the members of the Markush grouping would obviate this rejection. Claim 113 is vague and indefinite in the recitation "same (cytokine) superfamily" since it is unclear what superfamily Applicant is actually claiming. Amendment of claim 113 to more clearly define the claimed invention would obviate this rejection.

Claim 119 is vague and indefinite in the recitation "almost 50%" since it is unclear what range of inhibition is actually being claimed. Amendment of claim 119 to delete "almost" would obviate this rejection. Claim 123 is vague and indefinite in the recitation "significant inhibition" since it is unclear what amount of inhibition would constitute "significant inhibition." Amendment of claim 123 to more clearly define the invention would obviate this rejection. Claim 132 is vague and indefinite in the recitation "any of the method steps of claim 94" since it is entirely unclear what steps or groups of steps would result in the substance suitable for the method of claim 132. Amendment of claim 132 to delete "any of the steps" would obviate this rejection. Claim 126 is vague and indefinite in the recitation "The substance according to claim 125" since claim 125 is a method claim, not a composition or "substance" claim. Amendment of claim 126 to recite "The method of claim 125" would obviate this rejection. Applicant should be cautious about antecedent basis for the remainder of claim 126, if the above proposed amendment is used since at this time it is unclear to the Examiner precisely what Applicant intends to claim in claim 126.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 125-127 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to

make and/or use the invention for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Claims 125-127 appear to replace claim 78. The claimed invention is directed to methods of treating HIV by lowering antibody levels. As stated previously, Applicant has not established that lowering antibody levels by any of the claimed means would necessarily result in inhibition, suppression or cure of HIV. Indeed, one skilled in the art would reasonably conclude that lowering antibody levels in a host would favor the HIV infection rather than suppressing or inhibiting the infection. Nor does the specification establish that lowering **any** antibody level would result in inhibition of HIV infection. In the absence of convincing objective evidence, the rejection is maintained.

Claims 94-132 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed invention is directed to methods and substances modified in any number of ways to produce any number of effects and alleged to be suitable in therapeutic methods of stimulating stem cell replication, treating and/or preventing HIV infection, or for gene therapy. However, it is well known by those skilled in the art that modification of peptides and proteins is a highly unpredictable process relying predominantly on trial and error. Applicant has encompassed considerable breadth in the scope of the claimed invention but has not provided sufficient teachings or working examples to allow one skilled in the art to make and use the claimed invention with a reasonable expectation of success and without undue experimentation. Modification of even a single amino acid of a protein can have dramatic and often disastrous results. In the case of antibodies and antigens, modification of a single amino acid of an antibody or an antigen

can result in decreasing or abrogating antigen-antibody interactions. In the case of hemoglobin, a single amino acid change results in sickle cell disease. Here Applicant has essentially claimed any modification or group of modifications but has not set forth sufficient teachings to give one skilled in the art a reasonable expectation of success in making and using the claimed invention without undue experimentation. Applicant's claimed invention essentially constitutes an invitation to experiment. This is not sufficient to meet the requirement of 35 U.S.C. § 112, first paragraph.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.

Robert D. Budens
Primary Examiner
Art Unit 1648

rdb
July 1, 2002